REMARKS

Status of the Application

Claims 1-15 are currently pending. Claims 1-10 and 14-15 have been withdrawn in response to a restriction requirement. Claims 11-13 are currently under examination.

Claim Amendments

Claim 11 has been amended to remove the Jepson language. Claim 11 has also been amended to recite that the SPRM is administered to a patient SPRM for a first dosing period to achieve a therapeutic effect. Support for the phrase "therapeutic effect" can be found on page 7, line 20. Claim 11 has also been amended to recite administering at least one progestogen during a second dosing period to induce a predictable return to menstruation. Support for the phrase "a predictable return to menstruation" can be found on page 3, line 18. Finally, claim 11 has been amended to recite that the gynaecological disorders to be treated are uterine fibroids, endometriosis, hormone replacement therapy, menorrhagia, metrorrhagia, dysmenorrhea, adenomyosis and peritoneal adhesions. Support for this claim amendment can be found on page 5, lines 25-30. No new matter has been added as a result of this amendment.

Double patent rejection

Claims 11-13 are provisionally rejected under 35 U.S.C. Section 101 as claiming the same invention as that of claims 11-13 of copending Application No. US 2005/0215536. Applicant respectfully traverses this rejection.

Applicant wishes to hold this rejection in abeyance until notification from the Examiner that all of the remaining rejections in connection with this application have been removed. Upon receipt of such notification, Applicant will take the necessary steps to remove this rejection

Rejection of Claims 11-13 Under 35 U.S.C. Section 102(b)

Claims 11-13 are rejected under 35 U.S.C. Section 102(b) as being anticipated by WO 01/26603. According to the Examiner WO 01/26603 teaches a method of treating a gynaecological disorder (female contraception) by administering to a patient a SPRM for a first dosing period. The Examiner also states that the second dosing period comprises administering at least one progestogen, such as gestodene or progesterone. The mesoprogestin treatment component is administered for a period of 1 to 3 days (first dosing period) and the progestin component is administered for a period of 30 to 180 days (the second dosing period). The progestin compounds used are gestodene, progesterone and levonorgestrel and the

selective progesterone modulator compounds disclosed are J867, J912 and J956. Applicant respectfully traverses the rejection.

Applicant submits that WO 01/26603 does not teach each and every element of the claimed invention. Specifically, Applicant submits that female contraception is not a "gynaecological disorder". In addition, WO 01/26603 teaches about a new contraceptive regimen with a continuous or intermittent administration of a SPRM (mesoprogestin), with or without additional estrogen administration. Optionally, the invention in WO 01/26603 teaches about a sequential use of a SPRM (mesoprogestin) with a progestin. In this particular regimen, the long-phase (30-180 days) of progestin administration which is responsible for anovulation and contraception, is followed by a short phase (1-30 days) of SPRM administration, the purpose of which is to induce menses and prevent breakthrough bleeding.

The regimen described in WO 01/26603 differs drastically from the regimen of the claimed invention. The regimen of the claimed invention is based on a first dosing period of SPRM treatment to achieve a therapeutic effect and amenorrhea followed by a second dosing period of progestin treatment to induce a predictable return to menstruation in order to reset the endometrium for the next course of SPRM therapy thereby protecting against the development of undesired endometrial changes.

However, in order to expedite prosecution, claim 11 has been amended to recite that the gynaecological disorders to be treated are uterine fibroids, endometriosis, hormone replacement therapy, menorrhagia, metrorrhagia, dysmenorrhea, adenomyosis or peritoneal adhesions.

WO 01/26603 simply does not teach treating such disorders. Rather, as admitted by the Examiner, WO 01/26603 teaches a method for female contraception by administering to a patient a SPRM. According to WO 01/26603, optionally, the SPRM can also be administered in combination with an estrogen or used short-term, as menses inducer, after a long-term progestin administration (so called "mini pill") short term sequentially with a long-term progestin (mini-pill)

Therefore, because WO 01/26603 does not teach each and every element of the claimed invention, this rejection is now moot and should be withdrawn.

Objection of Claim 11

Claim 11 is objected to as being in an inappropriate Jepson claim. Applicant respectfully traverses this rejection.

Claim 11 has been amended such that claim 11 no longer reads as a Jepson claim. In view of the amendment to claim 11, Applicant submits that this rejection is now moot and should be withdrawn.

REQUEST FOR RECONSIDERATION

Reconsideration and withdrawal of all claim rejections are respectfully requested. Applicants believe that the present application is in condition for allowance. Should the Examiner have any questions or would like to discuss any matters in connection with the present application, the Examiner is invited to contact the undersigned at

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